

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING  
PHARMACY, INC. PRODUCTS LIABILITY  
LITIGATION

THIS DOCUMENT RELATES TO:

*Hanson v. Ocean State Pain Management, P.C.*  
1:13-cv-10685-RWZ

MDL No. 2419  
Dkt. No 1:13-md-2419 (RWZ)

**MOTION OF THE DEFENDANT, OCEAN STATE PAIN MANAGEMENT, P.C., TO  
DISMISS PRODUCT LIABILITY CLAIMS OF THE PLAINTIFFS**

Now comes the Defendant, Ocean State Pain Management, P.C., in United States District Court, District of Massachusetts, Civil Action No. 1:13-cv-10685-RWZ, and respectfully requests that this Honorable Court dismiss the Plaintiffs' product liability claims pursuant to Fed. R. Civ. P. 12(b)(6) and Local Rule 7.1. Applying Rhode Island product liability law, the Defendant avers that strict liability does not apply and that there were no breaches of warranties because the Plaintiffs' claims do not arise out of sales or transactions in goods. Further, the Defendant avers that the Plaintiffs' Short Form Complaint fails to state, or incorporate by reference, appropriate causes of action. Grounds in support of this motion are set forth in the attached memorandum of law.

Respectfully submitted,

By their attorneys,

A handwritten signature in black ink, appearing to read "SCAPPLIS", is written over a horizontal line.

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Dated: 11-4-15

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**MEMORANDUM OF LAW IN SUPPORT OF MOTION OF THE DEFENDANT,  
OCEAN STATE PAIN MANAGEMENT, P.C., TO DISMISS PRODUCT LIABILITY  
CLAIMS OF THE PLAINTIFFS**

Now comes the Defendant, Ocean State Pain Management, P.C., in United States District Court, District of Massachusetts, Civil Action No. 1:13-cv-10685-RWZ, and respectfully requests that this Honorable Court dismiss the Plaintiffs' product liability claims pursuant to Fed. R. Civ. P. 12(b)(6) and Local Rule 7.1. Grounds in support of this motion are set forth below.

## BACKGROUND

Over a number of years, New England Compounding Pharmacy, Inc., a/k/a New England Compounding Center (hereinafter “NECC”), supplied preservative-free Methylprednisolone Acetate (hereinafter “MPA”), a steroid used in pain medicine, to various physicians, pain clinics, hospitals, and other medical providers, including Ocean State Pain Management, P.C. (hereinafter “OSPM,” or “the Defendant”). On or about September 26, 2012, a recall of that medication was issued out of concern for fungal contamination of the medication in three “lots”

potentially provided to the Defendant. Litigation ensued and NECC was sued along with the Defendant and numerous other health care providers across the country. The litigation was consolidated through the Judicial Panel on Multi District Litigation in the District Court of Massachusetts, now before the Honorable Rya W. Zobel.

Abdul Barakat, M.D., a licensed physician board-certified in Anesthesiology and Pain Medicine, operated OSPM, an anesthesiology and pain medicine clinic with several facilities in Rhode Island, at the time of the product recall and subsequent meningitis outbreak. Contaminated medication from NECC was allegedly used at OSPM during the relevant time frame. Dr. Barakat was the physician who injected the medication into the patients during his procedures at OSPM. Neither Dr. Barakat nor OSPM has any affiliation with NECC other than to order medications, which they believed to be safe based on various representations of the company and others. Hundreds of other health care providers across the country ordered and used the same medications from NECC.

The Plaintiffs allege through a Short Form Complaint and Jury Demand, filed in the United States District Court of Massachusetts on February 14, 2014, that the Defendant failed to take due care in choosing the appropriate entity from whom to obtain preservative-free MPA. See Plaintiffs' Short Form Complaint and Jury Demand, Civil Action No. 1:13-md-10685-RWZ, Docket No. 5 (incorporating by reference the allegations in Plaintiffs' Second Amended Master Complaint, Civil Action No. 1:13-md-2419-RWZ, Docket No. 1719). The Plaintiffs allege that this failure caused injury to the Plaintiff, Margaret Hanson. Id. The Plaintiffs' Short Form Complaint states that it incorporates by reference claims of negligence, battery, product liability claims, agency, and civil conspiracy against the Defendant. Id.

The moving defendants deny all allegations of negligence and any and all other allegations of wrong-doing. The case is currently pending in the master docket for In re: New England Compounding Pharmacy, Inc., Products Liability Litigation, Civil Action No. 1:13-md-2419-RWZ, where common-issue discovery is ongoing. For the purposes of this motion, the Defendant will apply Rhode Island law given the fact that the Plaintiffs reside in Rhode Island, the Defendant's sole place of business is located in Rhode Island, and the administration of the NECC drug took place in Rhode Island. See id. at ¶¶ 2, 4 6.<sup>1</sup>

The Defendant now moves this court to dismiss the Plaintiffs' claims alleging product liability since the Plaintiffs fail to state claims upon which relief can be granted, pursuant to F.R.C.P. 12(b)(6).

### **LEGAL ARGUMENT**

#### **I. Standard of Review – F.R.C.P. 12(b)(6)**

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570 (2007)). Plausibility "is not akin to a probability requirement, but [requires] more than a sheer possibility that a defendant has acted wrongfully." Iqbal, 556 U.S. at 678. Thus, "[a] pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action' will not

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<sup>1</sup> If, for whatever reason, the Court decides to apply Massachusetts law to the instant action, the Defendant requests that the court refer to the Defendant's legal argument found in its Motion of the Defendants, Abdul R. Barakat, M.D., and Ocean State Pain Management, P.C., to Dismiss Product Liability and Consumer Protection Claims of the Plaintiffs, pertaining to the case Craig Simas, et al, v. Abdul R. Barakat, M.D., and Ocean State Pain Management, P.C., Civil Action No. 1:13-cv-10943-RWZ, filed simultaneously in the master MDL docket. The Defendant made the same argument for dismissal but relied upon Massachusetts law in the aforementioned motion.

do.” Id. When ruling on a motion to dismiss under Fed. R. Civ. P. 12(b)(6), the court accepts as true all factual allegations contained in the complaint, but not legal conclusions. Id.

## II. Standard of Review – Product Liability under Rhode Island law

To recovery under a strict liability theory in Rhode Island, a plaintiff must prove that: (1) defendant was engaged in the business of manufacturing, selling, or leasing the product at issue; (2) defendant manufactured, sold, or leased the product, which was in a defective condition and was unreasonably dangerous to a user or consumer; (3) the product was expected to and did reach the plaintiff user/consumer without substantial change from the time it was manufactured; (4) plaintiff user/consumer was using the product in a way that it was intended to be used; and (5) the defective condition of the product proximately caused plaintiff’s injuries. Raimbault v. Takeuchi Mfg. (U.S.), Ltd., 772 A.2d 1056 (R.I. 2001); Ritter v. Narragansett Electric Co., 283 A.2d 255 (R.I. 1971) (adopting Restatement (Second) of Torts § 402A).

The elements of a claim for breach of an express warranty in Rhode Island are found in G.L. 1956 § 6A-2-313.11. With respect to § 6A-2-313, “[t]he plaintiff who claims breach of express warranty has the burden of [pleading and] proving that the statements or representations made by the seller induced her to purchase that product and that she relied upon such statements or representations.” Thomas v. Amway Corp., 488 A.2d 716, 720 (R.I. 1985).

Claims for breach of the implied warranty of merchantability in Rhode Island are governed by G.L. § 1956 § 6A-2-314.12. “In order to establish liability for breach of the implied warranty of merchantability [in Rhode Island], a plaintiff ‘must prove that the product is defective, that it was in a defective condition at the time it left the hands of the seller, and that said defect was the proximate cause of the injury.’” Marketing Design Source, Inc. v. Pranda

North America, Inc., 799 A.2d 267, 272 (R.I. 2002) (quoting Lariviere v. Dayton Safety Ladder Co., 525 A.2d 892, 896 (R.I. 1987)); see Gray v. Derderian, 472 F. Supp. 2d 172, 182 (D.R.I. 2007).

Section 6A-2-315 prescribes the requirements for properly pleading a claim for breach of the implied warranty of fitness for a particular purpose. The “implied warranty of fitness for a particular purpose arises when the seller has reason to know the buyer’s particular purpose and that the buyer is relying on the seller’s skill or judgment to furnish appropriate goods and the buyer relies on the seller’s skill or judgment.” Lariviere, 525 A.2d at 897.

The Defendant’s argument is two-fold: (1) the Plaintiffs’ attempt to incorporate by reference the product liability claims referenced in the Master Complaint must fail since the Master Complaint’s product liability claims are only asserted against Tennessee defendants under Tennessee law, and the Plaintiffs failed to allege any product liability claims in their Short Form Complaint that would pertain to the Defendant; and (2) the Defendant cannot be found liable under Rhode Island’s strict product liability doctrine or for breaches of any warranties because it is not a “seller” or “manufacturer” of MPA within the meaning of § 402A and the applicable warranty statutes. Common to all of the above standards is the threshold requirement that “a plaintiff must prove that the defendant *sold* a defective product.” Scittarelli v. Providence Gas Co., 415 A.2d 1040, 1046 (R.I. 1980) [emphasis added]; Plouffe v. The Goodyear Tire Rubber Co., 373 A.2d 492, 495 (1977).

III. The Plaintiffs’ product liability claims must be dismissed because the Plaintiffs fail to allege or incorporate by reference any product liability claims applicable to the Defendant

In their Short Form Complaint, the Plaintiffs attempt to incorporate by reference several

causes of action laid out in the Master Complaint filed by the Plaintiffs' Steering Committee in the MDL docket. See Plaintiffs' Short Form Complaint and Jury Demand, Civil Action No. 1:13-md-10685-RWZ, Docket No. 5 (incorporating by reference the allegations in Plaintiffs' Second Amended Master Complaint, Civil Action No. 1:13-md-2419-RWZ, Docket No. 1719). Paragraph 9 of the Master Complaint reads as follows:

This master complaint is filed for administrative purposes only. It does not replace or supersede the complaints associated with existing civil actions. Plaintiffs' counsel will have an opportunity to sign on to facts and allegations set forth in this complaint through the Short Form Complaint mechanism. This complaint, standing on its own, only serves to provide a factual basis and sample counts for individual plaintiffs.

Merely stating the phrase "Count IV: Product Liability Claims (Against Clinic Related Defendants)" in a Short Form Complaint does not achieve the Plaintiffs' desired result. The Master Complaint's causes of action related to product liability are expressly limited to Tennessee defendants and only invoke Tennessee law. See Plaintiffs' Second Amended Master Complaint, Civil Action No. 1:13-md-2419-RWZ, Docket No. 1719 at ¶¶ 304-328. Plaintiffs are actually encouraged to add or amend allegations as they see fit, however, the Plaintiffs have failed to do so. See id. at ¶ 19. The Short Form Complaint is entirely devoid of any product liability causes of action arising out of Rhode Island law. See Plaintiffs' Short Form Complaint and Jury Demand, Civil Action No. 1:13-md-10685-RWZ, Docket No. 5. At most, the Complaint offers "labels and conclusions," which were deemed to be insufficient by the Supreme Court in Iqbal. 556 U.S. at 678.

Other individual plaintiffs recognized the need to add product liability claims, specific to their home jurisdiction, to their short form complaints. The Defendant has been sued by an additional plaintiff in the NECC MDL who initially filed his complaint in Massachusetts Superior Court. See Craig Simas, et al, v. Abdul R. Barakat, M.D., and Ocean State Pain Management, P.C., Civil Action No. 1:13-cv-10943-RWZ. There, the



plaintiff not only incorporated by reference several causes of action from the Master Complaint, he also added additional counts specifically pertaining to product liability in his Short Form Complaint. See Plaintiffs' Second Amended Short Form Complaint, Civil Action No. 1:13-cv-10943-RWZ, Docket No. 17. In fact, the product liability claims were the only additional counts that he felt compelled to include in his Short Form Complaint, presumably because he realized that the product liability causes of action in the Master Complaint were inapplicable to his case. See id. The Plaintiffs have failed to undertake the same efforts in the instant action, therefore, their product liability causes of action must be dismissed.

IV. The Plaintiffs' products liability claims must be dismissed for failure to state claims upon which relief can be granted

If the court does not dismiss the products liability claims based on the above argument, the claims still must fail due to the fact that the Defendant did not engage in a "sale" as required by the applicable Rhode Island statutes and Restatement (Second) of Torts, §402A. Even though the Plaintiffs did not state which types of product liability claims they are asserting against the Defendant, all of the available theories require a "sale of goods" and/or a "seller." Scittarelli, 415 A.2d at 1046 ("[A] plaintiff must prove that the defendant sold a defective product."); Plouffe, 373 A.2d at 495.

There is no law on hospital strict liability or any analogous claim in Rhode Island. The Defendant is unaware of any such claim ever being asserted against a healthcare provider in the state. The Defendant is unaware of any courts previously allowing such a claim to go forward to trial. However, most other states have addressed this type of scenario in recent years, and the

Defendant would refer the court to several relevant holdings, specifically ones concerning the provision of contaminated medication during a medical procedure.

In the majority of states, attempts to apply product liability principles to what would ordinarily be conventional malpractice actions against health-care providers have been unsuccessful. See, generally, Annotation, Liability of Hospital or Medical Practitioner under Doctrine of Strict Liability in Tort, or Breach of Warranty, for Harm Caused by Drug, Medical Instrument, or Similar Device used in Treating Patient, 65 A.L.R. 5th 357, 387-96 (1999).

Courts refer to the “essence of the transaction” test and policy considerations in finding that the provision of a medical instrument, drug, or prosthesis/implant was simply incidental to the essential business of medical treatment. Id. For patients who have sustained injuries from defective drugs, most courts have denied recovery against health-care providers in regard to both strict liability actions and breach of warranty claims, with only a few courts holding to the contrary. See id.

In Massachusetts, there is no strict product liability cause of action, and the breach of warranty theories are not available where “the predominant factor, thrust, or purpose” of the transaction is the “rendition of service, with goods incidentally involved.” Mattoon v. City of Pittsfield, 56 Mass.App.Ct. 124, 141 (2002) (quoting Bonebrake v. Cox, 499 F.2d 951, 960 (8th Cir. 1974)). In Mattoon, the court determined that the sale of water by a municipality did not equate to a sale of goods. Id. The court reasoned that the city did not create or manufacture the water, rather, it captured the water from brooks, streams, and rainfall, treated the water, and distributed it to its citizens. See id. The city charged a sum for the water, but that rate also reflected the cost of storage, treatment, and distribution. Id. Therefore, the court stated that it was clear that the predominant factor, thrust, or purpose of the activity was the rendition of

services and not the sale of goods. Id. at 141-142.

In the instant case, the Defendant did not create or manufacture the MPA, rather, it was ordered from NECC. The service (injection procedure) provided by Dr. Barakat was the predominant factor, thrust, or purpose of the transaction, and the medication itself was only incidentally involved. See id. The patient was not buying a medication product from OSPM to consume himself like a patient would when buying Tylenol. Mr. Simas was fully dependent on the skill and expertise of Dr. Barakat to inject the MPA into a specifically targeted portion of the back or neck using a large needle and fluoroscopic guidance. The procedure is highly complicated, and the patient is not capable of buying the product and performing the procedure himself. The Defendants were not engaged in the business of selling MPA separately for this purpose. Dr. Barakat examines and diagnoses patients and then performs an epidural steroid injection if the procedure is properly indicated. The injection procedure cannot be said to be anything other than the rendition of a service, specifically a “pain management” service, as stated in the defendant-clinic’s trade name. The provision of water in Mattoon was a service that required the expertise and faculties of the municipality in the same way that the provision of MPA required the expertise and faculties of Dr. Barakat and the employees of OSPM. See 56 Mass.App.Ct. at 141.

Various federal courts have held that a hospital cannot be subject to strict liability because it is not a seller or distributor of medical devices. See, Vergott v. Deseret Pharm. Co., 463 F.2d 12, 16 n. 5 (5<sup>th</sup> Cir. 1972) (holding that a hospital cannot be strictly liable under Texas law for a defective catheter because a hospital is “not a seller engaged in the business of selling the product.”); Roell v. Stryker, No. 3:06-cv-443, 2007 WL 2783357, at \*4 (S.D. Miss. Sept. 24, 2007) (holding that a hospital was fraudulently joined because it did not meet the definition of

“seller” as defined by Mississippi’s product liability statute or under the Uniform Commercial Code); Kavalir v. Medtronic, Inc., No. 07-0835, 2007 WL 1225358, at \*3 (N.D.Ill. Apr. 19, 2007) (holding that the hospital was fraudulently joined because hospitals are not sellers of medical devices and, therefore, there was no basis in Illinois law to support the plaintiff’s claims for strict liability and breach of implied warranty against the hospital); Pleasant v. Dow Corning Corp., No. 3:92-3180-7, 1993 WL 1156110, at \*3 (D.S.C. Jan. 7, 1993) (citing numerous state and federal decisions to support its holding that “because hospitals are primarily engaged in the business of providing medical services, rather than selling products, strict liability should not be imposed if the medical services involve the use of a product.”).

Numerous state courts have also entered decisions supporting the Defendant’s position, specifically with regard to the provision of medication. In Royer v. Catholic Medical Center, the court stated, “[M]edical services are distinguished by factors which make them significantly different in kind from the retail marketing enterprise.” 741 A.2d. 74, 78 (N.H. 1999). The court continued, “[A] healthcare provider in the course of rendering healthcare services supplies a product, the healthcare provider is not engaged in the business of selling products for purposes of strict products liability.” Id.; see also Moss v. Dartmouth-Hitchcock Medical Center, 2005 WL 3305010 at \*2 (D.N.H. May 12, 2005) (dismissing strict liability claim pursuant to the holding from Royer); Carmichael v. Reitz, 17 Cal. App. 3d 958 (1971) (barring strict liability reasoning that doctors sell services as healers of illnesses, that they prescribe medicine only as chemical aids to cure such illnesses, and that physicians diagnosing and treating patients are normally not selling either products or insurance); Osborn v. Kelley, 61 A.D.2d 367 (1978) (dismissing breach of warranty claim in a case involving the prescription of an unsafe drug because there was no “sale” of the drug by the physicians, the drugs were furnished as an incidental part of the

professional medical services rendered, and the physician was not in the position of a retailer); Shivers v. Good Shepherd Hospital, Inc., 427 S.W.2d 104 (Tex. Civ. App. 1968) (dismissing warranty and strict liability claims against a hospital in a case involving a bacterially contaminated drug because the court had previously limited such claims to only the manufacturer or distributor of the product); Dobisky v. Rand, 670 N.Y.S.2d 606 (App. Div. 3d Dep't 1998) (holding that state did not recognize a cause of action in breach of warranty for the performance of services in a case involving injectable pain medication, and there was no evidence of an express promise by the defendant to cure the decedent or to accomplish some definite result).

In Dove v. Ruff, a physician-allergist prepared an injectable medication using his own combination of solutions and sold it to a minor's parents, whose child then suffered an anaphylactic reaction. 558 N.E.2d 836, 839-841 (1990). Even in that instance, where the physician more closely resembled a compounder like NECC, the court granted summary judgment for the physician holding that the medication was not a product for purposes of strict liability under the state statute. Id. Furthermore, the fact that a separate charge was made on the bill for the medication did not make it a sale of medication as a separate transaction; the sale was simply incidental to the delivery of medical services. Id. The mixing and provision of medication equated to the "administration of a form of treatment" authorized by the state statute. Id.

The aforementioned cases represent the majority opinion held by courts across the country with respect to product liability claims against medical providers. Even in the rare case that applies the opposite holding, the courts have overturned or distinguished the prior ruling. In Karibjanian v. Thomas Jefferson University Hospital (applying Pennsylvania law), the court permitted the plaintiff to present evidence that the hospital was a seller of contrast medium

during the patient's cerebral arteriography. 717 F.Supp. 1081 (E.D.Pa. 1989). The court ruled in this manner despite noting the distinction in the Restatement (Second) of Torts, §402A, Cmt. (f) between suppliers of goods which also supply services and those suppliers who simply supply goods. Id. The court looked at the fact that the hospital owned an inventory of the substance which it kept until it supplied it to a patient via a physician, but the court ignored the fact that the substance was only provided in conjunction with medical services or procedures. See id. Not surprisingly, this holding was subsequently overruled by the Pennsylvania Supreme Court in Cafazzo v. Central Medical Health Services, Inc., 542 Pa. 526 (1995). The Cafazzo decision was then applied by the Supreme Court of South Carolina in In re Breast Implant Product Liability Litigation, 331 S.C. 540 (1998).

Based on the consistent holdings of the aforementioned cases, the Plaintiffs' allegations are clearly insufficient to support claims of strict liability or breaches of warranty against the Defendant and should be dismissed as a matter of law. The Defendant was engaged in the provision of a complicated medical service administered by a highly skilled medical professional with the so-called "good" only incidentally involved in the procedure. The provision of MPA in this instance in no way resembled a retail marketing enterprise, and "the predominant factor, thrust, or purpose" of the transaction was the "rendition of service." Mattoon, 56 Mass.App.Ct. at 141. Accordingly, the Defendant requests that the Plaintiffs' product liability claims be dismissed.

V. The court should adhere to its prior ruling on the Motion to Dismiss filed by the "Box Hill Defendants"

The court has already issued a ruling in another NECC MDL case in favor of the

Defendant's position. See Civil Case No. 1:13-md-2419 (RWZ), Docket Nos. 2225, 1642. On September 8, 2015, the court ruled on a motion to dismiss filed by Maryland defendants, Box Hill Surgery Centers, L.L.C., et al. (collectively the "Box Hill Defendants"). Id. The court held that Maryland's theory of strict liability does not apply to the sale of goods combined with the provision of medical services, when the provision of service predominates the sale of the good. See id., citing to Phipps v. Gen. Motors Corp., 278 Md. 337, 344 (1976); Burton v. Artery Co., 279 Md. 94, 109 (1977) ("whether [the contract's] predominant factor, [its] thrust, [its] purpose, reasonably stated, is the rendition of service, with goods incidentally involved (e.g., contract with artist for painting) or is a transaction of sale, with labor incidentally involved (e.g., installation of a water heater in a bathroom)" determines the applicability of strict liability); Roberts v. Suburban Hospital Assoc., 73 Md. App. 1 (1987). The court held that the provision of MPA was part-and-parcel with the service of its injection – the only purpose of the visit was the injection itself, something only a physician with special skill could provide. See Civil Case No. 1:13-md-2419 (RWZ), Docket Nos. 2225 at 5, 1642 at 10.

The instant case should hinge upon the same legal analysis given that Rhode Island law requires a "sale of goods" rather than a "rendition of service." See id.; Scittarelli, 415 A.2d at 1046 ("[A] plaintiff must prove that the defendant sold a defective product"); Plouffe, 373 A.2d at 495. Given that the court has already ruled that the provision of MPA by a pain clinic was part-and-parcel with the service of its injection, the Plaintiffs' claims requiring a "sale of goods" must necessarily fail. The purpose of the Plaintiffs' visit to OSPM was the injection itself, something only Dr. Barakat could provide given his medical expertise.



VI. Public policy concerns dictate that the Defendant should not be exposed to product liability claims pertaining to the provision of medication

Several courts have raised concerns regarding the public policy impact of labeling medical providers as “sellers” of medication or medical devices under theories of strict liability or breach of warranty. In Carmichael, the court noted that the art of healing frequently calls for a balancing of risks and dangers to a patient and that consequently, if injury results from the course adopted, liability should not be imposed on one seeking to save or assist the patient, barring negligence or fault by the physician. 17 Cal. App. 3d at 979 (citing Perlmutter v. Beth David Hospital, 308 N.Y. 100 (1954)); see also Osborn, 61 A.D.2d at 370.

In Kirk v. Michael Reese Hospital and Medical Center, the court partially relied on public policy concerns in holding that the imposition of strict liability on a hospital would not enhance the public interests in human life and health. 117 Ill. 2d 507, 523 (1987) (quoting Greenberg v. Michael Reese Hospital, 83 Ill.2d 282, 290-91 (1980)). To the contrary, noted the court, the imposition of strict liability might ultimately diminish the protection of human life which is entrusted to individuals and/or institutions which are pledged to protect human life. Id. If all medical care providers were suddenly exposed to such claims in the course of servicing their patients, the industry would not only be stricken with enormous monetary costs due to insurance concerns, but it would involve immeasurable human costs as well. The Kirk court was basically suggesting that providers would be disinclined to provide certain life-saving services or medications because they come with certain unfortunate, but necessary, risks. See id. The Defendant requests that the court keep these significant factors in mind when deciding the appropriate limitations of product liability in the instant case.



**CONCLUSION**

For the foregoing reasons, the Defendant respectfully requests that the Plaintiffs' claims alleging strict liability and breaches of warranties be dismissed for failure to state claims upon which relief can be granted.

Respectfully submitted,

By their attorneys,



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